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OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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**SUBJECT:** EFED Review of Public Comments in Response to the EPA EFED Revised

Environmental Risk Assessment for Atrazine

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The Environmental Fate and Effects Division (EFED) has reviewed many of the public comments in response to the Notice of Availability of Environmental Fate and Effects Assessment on Atrazine to Re-registration Eligibility Decision [OPP-34237A]. Comments from nine groups were considered by SRRD to address specific or general scientific issues and were referred to EFED for response. The following contains both summary and specific comments, and EFED's responses are listed below.

American Water Works Association (AWWA) Comment: AWWA expressed concerns that atrazine would contaminate ground and surface water, especially sources of drinking water.

**EFED Response:** The EFED and HED science chapters address the analysis of different studies of atrazine in surface and ground water, especially in sources of drinking water. These results and areas of uncertainty are discussed extensively.

**AWWA Comment:** AWWA indicated that they would like to understand the Agency's rationale for coordinating the different methodologies.

**EFED Response:** OPP and OW managers concluded that since the two offices were working

on atrazine during the same time period, there should be coordination between the two groups. The two groups compared the available toxicity data and shared studies, which improved the data bases for each risk assessment. The two risk assessment methodologies serve different purposes and make use of somewhat different approaches. Despite the differences in the two methodologies, however, the levels of concern for aquatic organisms were similar for both offices.

**AWWA Comment:** AWWA recommended that the results from the OPP and OW efforts be coordinated with the Office of Groundwater and Drinking Water (OGWDW).

**EFED/HED Response:** The coordination is ongoing, and copies of all documents are being shared between the offices.

Commenter: Center for Regulatory Effectiveness (CRE)

p. 1. **CRE Comment**: CRE was concerned that the Agency conducted a preliminary risk assessment and did not use and rely on a probabilistic risk assessment.

**EFED Response:** The atrazine eco-risk assessment first conducted a preliminary assessment using aquatic estimated environmental concentrations (EECs) based on the PRZM-EXAMS model. Because of the amount of monitoring data available on atrazine, EFED conducted the next tier of the atrazine aquatic risk assessment based on monitoring data. Both the preliminary assessment using EECs and risk quotients from the PRZM-EXAMS model as well as the refined assessment based on distributions of monitoring data for atrazine indicated low or no effects on fish and aquatic invertebrates. These results would very likely be the same for any fully probabilistic assessment.

Aquatic risks to fish and invertebrates based on EECs from the PRZM-EXAMS model were low for all acute endpoints (i.e., risk quotients were below 0.05, the lowest level of concern) and the risks were moderate for chronic effects (i.e., risk quotients were between 1 to 10). For direct effects of atrazine on fish and aquatic invertebrates, EFED determined that the risks were low and that there was no need for a full probabilistic risk assessment to show levels of low concern.

Risks to aquatic vascular plants were slightly higher than risks for chronic effects on fish and invertebrates. Comparison of toxicity values from three duckweed studies indicated that atrazine's toxic effects increase with the length of the test. Duckweed tests of 5-, 7- and 14-day exposures yielded EC<sub>50</sub> values of 170, 170, and 37 ppb, respectively. Increasing toxicity with longer exposures is consistent with the mode of action for atrazine, which is prevention of plant growth through blockage of photosynthesis. Without photosynthesis, the plant will consume its energy reserves and eventually die. If the plant is exposed for long periods, as is the case in ponds, marshes and other non-flowing waters, prolonged atrazine exposures would lead to the death of the aquatic plants as observed in the Kansas pond studies.

The Kansas pond studies showed reductions in the numbers of aquatic insects and young fish,

not from the direct effects of atrazine, but rather from the loss of vegetative habitat, an indirect effect. Current probabilistic risk assessment methods can not yet predict such indirect effects. Since the Agency has concluded that the major effects from atrazine use are indirect effects on fish and invertebrate populations, the probabilistic risk assessment can not address this problem.

p. 2. **CRE Comment:** The Agency did not use or rely on Syngenta's probabilistic risk assessment (PRA).

**EFED Response:** EFED did not assess risks using a fully probabilistic assessment for the reasons presented in the previous comment. With regard to Syngenta's PRA, the proper format for Tiers I and II were not followed, the monitoring data used in Tiers III and IV were not provided and the exposure models used have not been documented and peer reviewed. In addition, Syngenta did not address indirect effects from the loss of vegetative habitat. A full review and discussion of the Syngenta assessment is attached.

p. 3. **CRE Comment:** CRE stated that "According to EPA, there are inadequate data to perform a probabilistic risk assessment for atrazine...."

**EFED Response:** EFED agrees that there is an abundance of toxicity data for atrazine and that probabilistic methodology can be used. What has not been clearly stated is that there is not sufficient data on indirect effects, which can be severe on fish and aquatic invertebrate populations. Again, the current PRA model can not assess risks from indirect effects. EFED contends that there is "inadequate data" on indirect effects to assess risk, especially using PRA.

p. 5. **CRE Comment**: The theme throughout page 5 is that the Agency needs to quantify and use sound statistical and research methods for risk assessment.

**EFED Response**: As explained in response to comments by Syngenta, the atrazine effects of concern are indirect effects on the aquatic community due to the loss of vegetative habitat. For atrazine, the Agency has used monitoring data for its exposure assessment which is a higher level risk assessment than is commonly used in pesticide risk assessment. Currently, there is no methodology, including PRA, which can model and statistically analyze indirect effects. The Agency welcomes proposal of a statistical methodology to address indirect effects. Until a method is developed and peer reviewed, there is no basis to alter the Agency's aquatic risk assessment.

#### Commenter # 21: Northwest Coalition for Alternatives to Pesticides (NCAP)

A number of comments have been made by NCAP based on an EFED error which was made as the result of a misunderstanding of the nature of atrazine toxicity to aquatic plants at the time. In the Endangered Species section of the Atrazine RED, it was stated that "Atrazine levels of 20  $\mu$ g/L in streams and rivers are not rare occurrences and these concentrations may adversely affect aquatic vegetation, such that the loss of the vegetative habitat could affect populations of endangered aquatic invertebrates, especially crustaceans and the recruitment of young

endangered fish species."

- **EFED Response:** Effects found in the Kansas ponds on the loss of vegetative cover, were erroneously extrapolated to streams and rivers. Atrazine toxicity to plants is a function of the duration of time that atrazine exposure blocks the photosynthetic process. While it is not clear how long it takes atrazine to starve aquatic plants, it is known that atrazine effects are reversible after short-term exposures. Plants in rivers and flowing streams most likely would not be exposed to atrazine levels for a sufficient period of time to be killed. This error has caused some unnecessary expectation of problems for listed salmon. This does not mean that all endangered species concerns for salmon are gone. There is still a question about pesticide effects on olfactory functions and effects on the homing ability of salmon. EFED has identified this error and the text has been corrected.
- p. 1. **NCAP Comment**: "The atrazine ecological risk assessment is perhaps the most comprehensive risk assessment we have yet reviewed. The risk assessment has very few data gaps and also considers the extensive amount of water monitoring data available on this herbicide. The comprehensive information needs to be seriously considered by the Environmental protection Agency (EPA) as the risk assessment reveals massive and unreasonable ecological adverse effects resulting from proposed registered uses of atrazine."
- **EFED Response**: FIFRA requires a risk/benefit assessment for regulatory action. There is a wide range of toxicity and risks for various herbicides. The area of greatest variation among herbicides would appear to be their risks to non-target crops. It is important that one herbicide not be regulated and replaced with an alternative herbicide which poses greater risks to the environment. EPA has considered and used the wide variety of exposure and toxicity data available and concluded that atrazine is more likely to cause indirect effects than direct effects to aquatic animals.
- p. 2. **NCAP Comment**: "EPA's risk assessment indicates that mammals, birds, fish, aquatic invertebrates, and non-target plants are at risk from atrazine use."
- **EFED Response**: While this statement is true, the severity and type of effects is different for each. Herbicides, in general, alter vegetative habitats and may limit wildlife resources, which may force wildlife to move to poorer habitats and higher competition. There are no acute or chronic risks to fish and aquatic invertebrates from use on corn. The risks to fish and aquatic invertebrates are from indirect effects due to the loss of vegetative habitat. The risk quotients for non-target plants are generally low from spray drift (up to about 3) on standing plants, fairly high (up to about 24) for seedlings in dry areas, and high in semi-aquatic areas (up to about 200).
- p. 2. **NCAP Comment**: "The following points highlight the evidence in EPA's risk assessment that atrazine causes serious harm to salmon, their habitat and other aquatic species in the region. As it is the EPA's duty under the Endangered Species Act, we request that you consider all of the risks that this herbicide poses to listed salmon and their habitat. EPA must properly regulate atrazine by immediately canceling all uses."

**EFED Response**: There are five points that are important to understanding the risk assessment with respect to endangered species in the Pacific Northwest. First, the EPA risk assessment indicated that there were no acute risks to fish and the level of concern for endangered species was not exceeded. Second, it is unclear from the monitoring data whether the atrazine concentrations in streams in the region are likely to produce chronic or sublethal effects such that the risks would exceed levels of concern for fish and wildlife. Third, the migratory salmon are mostly found in flowing waters rather than lentic areas with no outlets which were modeled, and the Kansas ponds tested by Kettle et al. (1987). Fourth, atrazine concentrations in flowing waters are not expected to be as persistent as those found in ponds and other lentic habitats. Atrazine reacts quickly in plants to block photosynthesis, and recovery from short-term exposures is fairly rapid in clean water. Therefore, it is unlikely the vegetative losses in flowing waters will be as severe as those reported in the Kansas ponds. Fifth, the scientific evidence on effects on the olfactory function of homing adult salmon needs to be verified. The U.S. Wildlife Service and/or NOAA are working with salmon to measure the effect of carbofuran, diazinon and atrazine on homing ability in pesticide-exposed salmon. If the atrazine effects on salmon homing are confirmed. EPA will need to evaluate the risks using atrazine concentrations for the appropriate region.

p. 2. **NCAP Comment**: "EPA's general effects characterization of atrazine states that 'data strongly suggest that atrazine will have direct negative impact on freshwater and estuarine plants as well as indirect effects on aquatic invertebrate and fish populations which rely on vegetative habitat for predator avoidance and sensitive organisms that are lower on the food chain. Concentrations of atrazine measured in surface waters suggest that negative impacts on aquatic ecosystems are occurring."

**EFED Response**: Aquatic vegetative losses due to atrazine result from prolonged exposures which block the photosynthetic process until the plant has consumed all its stored energy reserves and dies. The length of time it takes atrazine to starve aquatic plants to death is uncertain. It appears that it takes weeks if not months of aquatic exposure to cause significant losses in aquatic vegetation. Atrazine exposures of this duration are only found in lentic habitats (i.e., ponds, lakes, marshes, possibly in intermittent streams in areas of infrequent rain and in confined estuarine areas). It is doubtful that atrazine concentrations will persist long enough in one area in flowing water to cause persistent vegetative losses.

p. 3. **NCAP Comment**: "EFED also notes that 'there are inevitably' other pesticides present in contaminated water that, combined, would alter the 'levels at which individual chemicals such as atrazine cause impact.' (page 11) At this time, a comprehensive understanding of these effects is not known. Until this information is available, the use of any atrazine product must be prohibited."

**EFED Response**: The citation above refers to evidence that combinations of pesticides can have interaction effects (i.e., additive, antagonistic or synergistic). Atrazine appears to be synergistic with organophosphate pesticides and some herbicides. More data are necessary to determine the

interactive effects of atrazine and other pesticides, the concentrations at which such effects would occur, and the likelihood of co-occurrence of the pesticides in water at those concentrations.

p. 3. **NCAP Comment**: "Atrazine is persistent. An anaerobic aquatic study gave its half-life in water as 588 days (page 45) and Klassen & Kadoum (1979) found 'atrazine to have an estimated half-life of six to eight months in a farm pond ecosystem.' (page 54) The potential for atrazine and its degradates to accumulate and persist results in unacceptable impacts to aquatic ecosystems."

**EFED Response**: Atrazine is persistent and residue levels might accumulate in lentic habitats. It is highly unlikely that atrazine concentrations would accumulate in flowing waters. The NAWQA data for atrazine are mostly measured from flowing waters. Historical monitoring data have shown a seasonal variation in atrazine concentrations in streams.

p. 3. **NCAP Comment**: "The USGS has detected atrazine in surface waters [NAWQA] in Washington, Idaho, Oregon, and California used by salmon species listed as threatened or endangered under the Federal Endangered Species Act. In Oregon, atrazine was found at levels above USGS recognized aquatic life criteria. Because of its impact, atrazine should not be allowed to contaminate the surface waters utilized by salmon."

**EFED Comment**: It is uncertain which aquatic life criteria value was compared to the Oregon NAWQA data. The EPA's Office of Water has recently evaluated the toxicity data on atrazine and proposed aquatic life criteria for atrazine for public comment. The proposed water quality values are as follows:

OW, Water Quality Criteria for Atrazine (ug/L)			
	Final Acute Value	Fish Chronic Value	Invertebrate Chronic Value
Freshwater Criteria	657.3	11.56	85.11
Saltwater Criteria	641.5	11.28	83.06

The samples taken by the NAWQA program in Oregon and in most other NAWQA study units represent water bodies of varying sizes. The potential effects on salmon suggested by the NAWQA data would be better assessed by considering the concentrations of atrazine detected in streams populated by salmon in this region. The Agency has not performed a regional risk assessment for atrazine with this level of detail.

p. 4. **NCAP Comment**: "Atrazine levels of 20 g/L [sic -  $\mu$ g/L] in streams and rivers are not rare occurrences and these concentrations may adversely affect aquatic vegetation, such that the loss of the vegetation habitat could affect the recruitment of young endangered fish species.'

(Page 74) Atrazine use is 'estimated to yield surface water concentrations which exceed a number of non-standard, sublethal toxicity levels reported in the literature for a number of fish species and exceed concentrations which have indirect community effects on aquatic species. Indirect effects on fish and aquatic invertebrates are severe due to the loss of 60 to 95 percent of the vegetative cover, which provides habitat to conceal young fish and aquatic invertebrates from predators.' (page 60) This is another example of how proposed allowable uses of atrazine pose great risk to the survival of fish species."

**EFED Response**: The above statement was made in the Atrazine RED based on the effects reported in Kansas ponds. As stated in response to other comments, the toxicity mechanism affecting losses in vegetative cover occur as a result of prolonged exposure to atrazine which starves the plant to death. How long that process takes for vascular plants in uncertain. It may take longer than 4 weeks, as indicated in estuarine microcosm tests which showed no effects on mollusk growth after 28-day exposure at  $20~\mu g/L$ , but in which clam and oyster growth were significantly reduced after 60 days (Dr. Geoff Scott, NOAA, Charleston, SC, personal communication). It is much less likely that vegetation in streams and rivers will be exposed to atrazine concentrations of  $20~\mu g/L$  in flowing waters for periods long enough to have an adverse effect on vegetative cover. Therefore, this conclusion in the Atrazine RED has been changed to reflect effects which are limited to lentic (non-flowing) water bodies.

p.4. **NCAP Comment**: "Also, uncertainty 'exists concerning the extent of atrazine effects on homing and reproduction in endangered salmon and other anadromous fish species.' (Page 74) These effects are being found at notably low concentrations in laboratory studies. This is of significance to the reproduction of listed salmon, because existing concentrations in streams inhabited by endangered salmonids may exceed these levels for prolonged periods. (page 74) The direct, sublethal, and indirect effects that atrazine has on fish must be dealt with in a manner that reflects the responsibility EPA has as a federal agency to protect listed species."

**EFED Response**: The highest atrazine application rate on crops which are grown in the Pacific Northwest is 2.0 lbs ai./A. At this rate, the risk quotients for farm ponds did not exceed the level of concern for endangered species. Concentrations in streams and rivers would likely be less than the exposures for a farm pond and the exposures are certainly of shorter duration than ponds. As stated in the preceding EFED response, atrazine exposures to aquatic plants in streams would be too short in duration and unlikely to affect vegetative cover. The only potential source of risk to salmon would be from sublethal effects on olfactory nerves which inhibit their homing ability. As previously stated, this effect on olfactory function with respect to homing is being investigated by US National Marine Fisheries.

p. 5. **NCAP Comment**: "These findings show that the proposed EPA regulation of atrazine fails to adequately mitigate risks to fish."

**EFED Response**: The Agency has not yet reached the stage for mitigation. The reregistration process involves several steps. There is the development of the Agency risk assessment. The public comment period allows the public to identify inaccuracies in the risk assessment and to

provide additional information relative to the possibility of risks. Once the risks have been identified, then the mitigation process begins. Sometimes there are uncertainties which require additional testing and investigation before the potential risks are confirmed and then mitigation measures are revisited.

p. 5. **NCAP Comment**: "The death of any individual in a threatened or endangered species' population is unacceptable and makes recovery efforts that much more difficult. This herbicide can not be regulated in such a manner that it is kept out of water. Therefore, atrazine use must be prohibited."

**EFD Comment**: FIFRA requires that risks be balanced against benefits. If the determination is made that risks to endangered species exist, the balance between risks and benefits is weighted more toward the risk and risk management will have to address the issue, which could include prohibiting atrazine use in critical areas. At this point the risks to listed salmon species are uncertain and require more research on the effects of homing ability.

### Commenter # 24: The Weed Science Society of America (WSSA)

p. 1. **WSSA Comment**: "As matters of substance there are several significant shortcomings in the analysis. These include reliance on worst-case interpretations using worst-case data without discussion of the data's variance from other studies. Because a relatively small number of studies drive the worst-case analyses it would be worthwhile to note whether they have been confirmed by other published results from subsequent studies. Also, many of the studies cited were completed before the significant rate and practice changes that occurred in the early 1990's, yet no discussion of the positive impacts of these changes was noted. In addition, the historical record of incident reports has not been given adequate weight or interpretation in this assessment. Finally, several conclusions are drawn or implied about aquatic and terrestrial ecosystem impacts based on single species effects, but these secondary indirect effects appear to be conjecture lacking substantiation."

**EFED Response**: The atrazine exposures were based on monitoring data. Consequently these are not worst-case data, because the monitoring programs were not designed to measure atrazine when applications were made or in areas of high use. The toxicity data are not worst-case data because the lowest toxicity values are surrogate data for the many species which exist within each taxonomic group. It is well-known that none of the standard test species consistently represent the most sensitive species within each group. If the goal is to protect biodiversity, the use of the lowest toxicity values is not worst-case data. A number of supporting studies were identified at 1  $\mu$ g/L and at 20  $\mu$ g/L which resulted in indirect effects on different taxa in the aquatic community.

p. 2. **WSSA Comment**: "Of all the studies referenced only the highest recorded concentrations of atrazine are used for comparison with the most sensitive endpoints found. As a result the cumulative exceedence graphs used in the assessment are not representative."

**EFED Response**: These comments were addressed in the previous response.

p. 2. **WSSA Comment**: "A different analytical approach such as the probabilistic analysis now used for human exposures could do a better job of describing the magnitude of environmental risk by including more of the relevant data. It is our understanding that several groups including the EPA-FIFRA Science Advisory Panel (SAP) have recommended that a probabilistic method be used and we endorse that approach."

**EFED Response**: As explained in response to comments from Syngenta, the aquatic risks from direct toxicity are generally low. The area of greatest concern is from indirect effects caused by the loss of vegetative cover for young and small fish and aquatic invertebrates. While the effects of highest concern are due to indirect effects, there is no existing methodology in PRA to address risks from indirect effects.

p. 2. **WSSA Comment**: "A 'weight of the evidence' interpretation of the Ecological Incident Information System (EIIS) incident reports from 1991 to 1998 should lead to a more positive interpretation than has been presented. These incident reports cover eight years and approximately 400 million acres of atrazine application over a broad range of geographic and climatic extremes. Only 44 incidents (about 1 per 10 million acres) were deemed to have probable or highly probable associations with atrazine. Of these, nearly 70 percent are economic crop damage reports, not ecological impacts. The thirteen probable ecological incidents represent only 1 incident per 33 million acres of application and all of these incidents lack sufficient data to ascertain that atrazine truly caused the incident. From many perspectives this is a strong indication of low environmental risk."

**EFED Response**: The incidents per million acres analysis presented above would be appropriate if there were assurances that all incidents were reported. Since not all incidents are reported, any conclusions about the incidents must be qualified. EFED uses the incidents to try to better determine whether there may be problems with a pesticide. Any quantitative analysis beyond that may be speculation.

p. 2-3. **WSSA Comment**: "Several extrapolations from single species effects to ecological community effects are included in this assessment. An example in the last paragraph on page 7 that states, 'Herbicide effects on wildlife are not normally acute in nature. Rather, the herbicide can alter the types of vegetation or reduce food sources in the habitat such that the animal populations must move elsewhere and possibly to a less suitable area. Thus herbicides affect animal populations by reducing favorable habitat and increasing competition among species for nesting and food resources." This statement is repeated nearly verbatim on page 66, but no studies have been cited to support these assumptions."

**EFED Response**: The reference for this conclusion will be added to the text. This text reflects the conclusions of Freemark and Boutin of the Canadian Wildlife Service (1994). The citation was listed in the references, but it was inadvertently omitted from the text. Freemark and Boutin reviewed the literature for effects and their "Literature Cited" extends for 17 pages with about

14 literature citations per page.

- p. 3. **WSSA Comment**: "Likewise, on page 20, cascading aquatic plant community responses to atrazine in ponds are extrapolated to extremes including release of nutrients, increased phytoplankton growth, decreased light penetration, increased plant mortality, increased sedimentation and loss of vegetation which result in heavy predation of small fish and invertebrate populations. The only reference cited, Kettle *et al.* 1987, appears to support one endpoint but not necessarily the conjectured pathway. This study was also conducted in artificial ponds and has not apparently been verified in bona-fide aquatic communities."
- **EFED Comment**: This is a natural progression of effects which starts with the death and decay of aquatic vascular plants. Plants die and release nutrients, the absence of plants increases the suspension of sediments by water movement, the nutrient release increases bacteria and resistant phytoplankton population growth, sediments and algal blooms reduce light penetration, reduced light penetration increases benthic vegetative losses even for pesticide resistant plants, and losses in vegetative habitat cause high predation pressures on small fish and aquatic invertebrates. All these effects have been reported by various authors included in the RED references, even to the point of quantifying the reduction in photosynthesis from sediments on plant leaves (Jones and Estes, 1984). Also see Hurlbert (1975), Secondary effects of pesticides on aquatic ecosystems.
- p. 3. **WSSA Comment**: "Finally, because this ecological risk assessment is part of a FIFRA enabled risk benefit analysis, it is important to contrast this certainty of the benefits with the uncertainty of the described risks. Weed scientists can speak with extensive experience and scientific certainty about the uses and value of atrazine. WSSA members have studied atrazine's performance and economics in numerous agronomic, specialty, and ornamental crops as well as in right-of-way and industrial situations. During the special review process, WSSA and many individual members have spoken and submitted comments about the substantial economic benefits of atrazine"

**EFED Comment**: Uncertainties in the ecological risk assessment are discussed in the RED. The Agency will consider these uncertainties, along with uncertainties in the benefits analysis, when considering risk management.

## Commenter # 001. Sipcam Agro USA, Inc.

p. 1. **Sipcam Agro Comment**: "The use of 'open literature' ecotoxicological data is risky at best to rely on rather than the guideline studies conducted under GLP and submitted by atrazine registrants. It allows reviewers to 'cherry-pick' data that creates a worse 'worst-case scenario'. An honest apprasal [sic] of the data submitted must be conducted using sound science. The Science Advisory Panel (SAP) must be convened in order to insure that all relevant data is considered with regard to the ecological fate and effects of atrazine before the Registration Eligibility Decision document is issued."

**EFED Comment**: The comment on "worst-case scenario" was addressed above. The monitoring data are not worst case and the use of the lowest toxicity values as surrogate data for the numerous species within a taxonomic group is not overly conservative. Standard test organisms are not consistently more sensitive than other species in the taxon. Outside studies are used as supplemental data. Field effects such as those seen in mesocosm studies could not be captured by guideline laboratory studies.

The methods used in the atrazine risk assessment have been peer reviewed by the Science Advisory Panel many times. The public comment process and technical briefing were designed to give the opportunity for further scientific comment.

- p. 1. **Sipcam Response**: EPA must clarify why the "... data did not appear to be appropriate for probabilistic analysis". EPA missed a golden opportunity to go beyond the Tier I/II deterministic risk assessments (DRA) looking at worst case scenarios by not using the extensive data set of any pesticide to perform probabilistic risk assessments (PRA) on atrazine."
- **EFED Response**: This comment has been addressed in detail in response to comments by others above. The areas of highest concern were effects on terrestrial and aquatic plants and indirect effects, as stated in responses above to the same question by other authors in greater detail. The PRA model can not quantify risks due to indirect effects.
- p. 2. **Sipcam Comment**: "Is the Agency relying on scientific data in reference to 'synergism and indirect effects' or is this a purely speculative statement. Most incident reports, unfortunately, do not contain enough factual information to make unequivocal conclusions as to the cause. The Agency rightly recognizes this in an earlier statement in this paragraph, 'In none of these cases has evidence been provided that firmly demonstrate that atrazine has produced the reported effects.'"
- **EFED Response**: The fish kills co-occurring with atrazine applications are difficult to understand based on straight toxicity of atrazine to fish. Many authors have reported synergistic effects with atrazine and many other pesticides which were summarized in the back of Appendix XI. Ecological Effects Characterization. For example, atrazine and chlorpyrifos are synergistic and both pesticides are applied to corn about the same time. In this case, atrazine enhances the toxicity of chlorpyrifos. Another possibility is that atrazine, which stops photosynthesis in plants and/or organic matter in the runoff, may reduce dissolved oxygen and the low DO kills the fish. All this is possible, but it is speculation at present.

The indirect effects due to vegetative loss are based on studies cited in the RED (e.g., Kettle, et al, 1987). Further details are given in response to similar comments by Syngenta.

p. 3. **Simcam Comment**: "This paragraph infers that atrazine caused or contributed to the crop injury identified, however, EFED failed to note that the symptoms identified are classic metolachlor injury to corn not atrazine."

**EFED Response**: Fourteen incidents with corn were reported by Novartis. In all cases atrazine was used in a tank mix with one or more herbicides, usually with Bicep II Magnum (i.e., an atrazine/ metolachlor mixture). Without toxicity data on the two herbicides tested individually and together, it can be assumed that each pesticide has added some measure of toxic effects, if the two pesticides have herbicidal properties.

# Commenter # L002. Maryland Department of the Environment (MDE)

p. 1. **MDE Comment**: "The US EPA has generated draft ambient water quality criteria (thereafter, Document) for the herbicide atrazine."

**EFED Response**: The draft ambient water quality criteria document was written by the EPA Office of Water (OW) and they have been accepting comments on this document.

p. 2. **MDE Comment**: "Exposures as low as ½ the growth EC<sub>50</sub> resulted in increases in low molecular weight molecules and decreasing percent of protein composition per cell with atrazine exposure. These alterations may affect the nutritional content of microalgae, with possible effects on higher trophic levels such as primary consumers (e.g., oysters). (Weiner, et. al. 2001)."

**EFED Response**: The article by Weiner *et al.* (2001) was published after the completion of the atrazine risk assessment. If this article has been interpreted correctly, the changes in cellular nutrient may be another example of indirect effects of atrazine on the aquatic community. Unfortunately, MDE failed to identify the journal source.

# Commenter # L003. Natural Resources Defense Council (NRDC) and World Wildlife Fund (WWF)

p. 4. **NRDC** & **WWF** Comment: "Another mode of action involves stimulation of aromatase activity, thereby increasing endogenous conversion of androgens to estrogens. This mode of action has been supported by work in fish, alligators, frogs, and human cells. Recent work indicates that there may be no biologically-identifiable threshold for this latter mode of action. In fact, atrazine may disrupt hormonally-regulated development in amphibians at levels below ambient levels in many U.S. water bodies."

**EFED Response**: EFED has not yet seen evidence of these effects except the association of atrazine and feminization of male alligators in lake Apopka, Florida; but no confirmation of cause/effects has been seen.

p. 5. **NRDC** & **WWF** Comment: "Brook trout, among the most sensitive aquatic animal, has a chronic NOAEC value of 65 ppb, and fish populations are likely to suffer reductions due to food loss and habitat damage at 20 ppb.

**EFED Response**: The extrapolation of vegetative losses in the Kansas ponds to flowing waters

was an unfortunate error. The effect of atrazine on aquatic plants is time dependent. Atrazine effects on plants can be reversible, if the exposure is not long enough to starve the aquatic plant to death. It is unlikely that the duration of atrazine exposure in flowing waters is sufficient to kill vascular aquatic plants. Hence fish populations in flowing waters are unlikely to suffer reductions due to food loss and habitat damage at 20 ppb.

p. 6. NRDC & WWF Comment: "Bluegill (a very hardy species) was reduced 96% in a year."

**EFED Response**: Qualification of this statement is that bluegill recruitment was reduced 96%, not its population.

p. 7. **NRDC** & **WWF** Comment: "A glaring omission in EPA's Atrazine Environmental Fate and Effects Chapter is its failure to provide a scientific framework for translating its findings about the multiple individual biological impacts of atrazine exposure into conclusions about the ecological significance of the risks posed by the chemical. That is to say, although EPA presents atrazine's effects on numerious biological endpoints standing alone (terrestrial plants, birds, etc.), the agency does not attempt to express what these individual concerns mean at the level of ecosystems."

**EFED Response**: EPA followed the tiered risk assessment format and focused the next tier on those risks which were considered greatest. Hence, the focus on risks was on aquatic plants and indirect effects on the aquatic community.

There are many uncertainties with assessing chronic risks to birds and mammals, especially for herbicides. For example, the predicted residue levels are upper level and residues on vegetation can be washed off by rain or irrigation, which reduces the period of exposure. If the herbicide kills the typical vegetation present in a wildlife's diet and makes it unpalatable, the exposure period is limited. Freemark and Boutin (1994) conclude that herbicide use typically forces birds and mammals to move to less desirable habitats when wildlife resources are limited. Wildlife select the most desirable habitat; therefore, when they move away from herbicide-treated areas it is into less favorable areas and probably with increased competition.

p. 7. **NRDC & WWF Comment**: "In its Guidelines for Ecological Risk Assessment (USEPA, 1998), EPA provides three phases for ecological risk assessments - problem formulation, analyses, and risk characterization. None of these were undertaken here. To the contrary, EPA has merely compiled scientific information relevant to the issue at hand in isolation from the decision it will ultimately be required to make on re-registering atrazine. The agency does not frame a decision context for this information, articulate the decision to be made, or even describe potentially conflicting public values involved in interpreting the scientific data present."

**EFED Response**: A more complete discussion of problem formulation and endpoint selection has been included in the revised RED chapter, along with the risk characterization. The order of work has been for EFED to present management with the risks. The RED science chapter documents do not present regulatory options or articulate the decision to be made. In fact, these

would be premature until public comments on the risk assessment have been considered. Most of these issues are addressed during the risk management process, which occurs after the Agency response to public comments and revision of the RED document.

p. 8. **NRDC** & **WWF** Comment: The commenters described the results of recent work by Dr. Tyrone Hayes of the University of California at Berkeley on the African clawed toad (*Xenopus laevis*) exposed to atrazine. They indicate that effects included abnormal gonadal development, feminization, hermaphroditism, and reduction in the size of the laryngeal muscle used for mating calls. Data on reproduction rates are not yet available.

**EFED Response**: EFED has reviewed the attached study by Dr. Tyrone Hayes and a similar article which he submitted for publication on the effects of atrazine on the African clawed frog (*Xenopus laevis*). The reported NOAEL was 0.01  $\mu$ g/L and the LOAEC was 0.1  $\mu$ g/L based on males with abnormal or multiple gonads. The following adverse effects were reported on the male African clawed frog at metamorphosis: at  $> 0.1 \mu g/L$  males had multiple gonads or were hermaphrodites (never found in over 10,000 controls); at  $\geq 1.0 \,\mu\text{g/L}$  males had smaller inside diameter larynges than controls; at 25 and 200  $\mu$ g/L in the second, but not the first, experiment males and females were smaller than controls in length (i.e., snout to vent) and body weight. No raw data were submitted to analyze for significant effects or to determine the percentage of males affected or the degree of reduced growth. While all of these effects were within environmental concentrations of atrazine found in many aquatic areas, it is not clear if the effects on gonads and reduced diameters in larynges have any effect on reproduction and populations, which were concerns expressed by the commenter. Dr. Hayes expressed the belief that "Ongoing investigations of the effects of atrazine on other species and amphibians in the wild will assess the realized role of this widespread compound [atrazine] in amphibian declines." Unless these effects on amphibians are shown to have adverse effects on reproduction and the population, it is unlikely that the Agency would regulate atrazine on these effects on gonads and larynges. It was suggested to Dr. Hayes that he should continue his experiment through reproduction to determine if these results have an adverse effect on reproduction (personal communication, March 13, 2002).

p. 9. **NRDC** & **WWF** Comment: "Significantly, the prediction of widespread, subtle, yet devastating effects on wild amphibians proved correct when U.C. Berkeley researchers collected frogs from the wild (*Rana pipins*), across the U.S., they found a very high prevalence of freeranging frogs with gonadal abnormalities, consistent with the prior laboratory observations of atrazine exposure. Of the affected frogs, 100% were found in the Midwest, where the highest levels of atrazine, alachlor, and metolachlor are found in the water (all endocrine disrupting pesticides in common use in the Midwest), and 0% were found in the West. Thus, this phenomenon is clearly not an artifact of laboratory testing."

**EFED Response**: A prepublication scientific paper by Dr. Hayes, Univ. of California at Berkeley was attached with the comments. Dr. Hayes (personal communication, March 13, 2002) indicated that 100 wild frogs (*Rana pipins*) were collected at 7 sites and that the male frogs (about 50 per site) either showed no gonadal abnormalities or else all males showed

gonadal abnormalities (personal communication, March 13, 2002). As with many field monitoring studies, when a variety of chemicals are present or have been used at a site, it is difficult to assign causation of effects to one or more of the chemicals. As indicated by the commenters, alachlor and metolachlor (both endocrine disruptors) are used in the same areas as atrazine. While there is uncertainty about which chemical or chemicals caused the effects, the field survey indicates that the gonadal effects observed in the laboratory also occur in wild populations in pesticide-treated areas. It is unclear whether the affected frog populations in these sites are capable of reproduction or if the population is totally dependent on immigration from unaffected populations. Again, it is important to demonstrate that the effects found on male gonadal development and larynges have an effect on survival and/or reproduction. Dr. Hayes indicated that the **preliminary test results** show that males with effects on gonadal development produce no sperm (personal communication, March 13, 2002). EFED has expressed interest in the ongoing research on these frogs to answer the questions on reproduction.

p. 9. **NRDC** & **WWF** Comment: "Second, the reproductive effects observed in frogs indicates that there may be no clear threshold for the effects of atrazine on sexual differentiation in amphibians, making exposures at current environmental levels an imminent hazard to wildlife and to endangered species."

**EFED Response**: The study provided with this comment reported that there was a no effect level for atrazine effects on male *Xenops* gonadal abnormalities at  $0.01~\mu g/L$ . Atrazine effects on frog gonadal development have been demonstrated in the laboratory. Similar effects have been found in *Rana pipins* in areas were atrazine and other endocrine-disrupting pesticides have been used. What is not certain at this time is whether the gonadal abnormalities have an effect on reproduction. Extrapolation from atrazine effects on an amphibian to an "imminent hazard to wildlife and to endangered species" raises concerns for risks, but the warning is premature until there is credible evidence that these effects are affecting the reproduction of amphibians.

p. 11. **NRDC & WWF Comment**: "Aside from any direct carcinogenic actions of atrazine, there is evidence that the herbicide may interact with nitrate fertilizers in the environment to form a more potent carcinogen, N-nitrosoatrazine (NNAT). Weisenburger *et al.* found that NNAT is readily formed when atrazine is combined with nitrite in acid conditions in the soil or in the stomach. The authors concluded that, given the frequent coexistence of atrazine with nitrate fertilizers in agricultally contaminated water, the potential carcinogen NNAT may be a common exposure accompanying atrazine use. Therefore, NNAT formation may be an underlying mechanism in the initiation of atrazine-associated non-Hodgkin's lymphoma.

In 1993 Meisner *et al.* tested NNAT on humans to assess its genotoxicity. When human lymphocytes were exposed to very levels of NNAT (concentrations as low as 0.0001 micrograms/ml) chromosome damage was induced. The authors concluded that 'the increased incidence of stomach cancer, leukemia and lymphoma in farmers, who have the greatest exposure to both nitrates and atrazine, raises concerns about the safety of water supplies that contain both of these contaminants.'"

**HED Response**: HED appreciates the seriousness of this comment, and acknowledges that N-nitrosoatrazine has not been included in the risk assessment for atrazine. OPP focused the atrazine risk assessment on the significant known hazards (endocrine disruption) and exposure pathways (drinking water) associated with atrazine for which reliable exposure data were available. In particular, OPP was careful to incorporate the chlorometabolites into the assessment, and considered them to be of equivalent toxicity to the parent compound.

Since N-nitrosoatrazine can be formed *in vitro* when atrazine and nitrite are mixed at an acid pH (Wolfe, et al., 1976), and because atrazine and nitrites can occur together in drinking water, it has been hypothesized that it is possible that N-nitrosoatrazine could be formed at acid pH in the stomach. However, formation of N-nitrosoatrazine *in vivo* has not been demonstrated. N-nitrosoatrazine has been shown to be mutagenic in genotoxicity tests, but cancer bioassays in female mice and rats failed to show a carcinogenic response following N-nitrosoatrazine exposure (Weisenberger, 1990 - abstract). OPP is exploring the extent of this compound's presence in drinking water with the OW and the registrant.

**EFED Response:** *In vitro* effects, such as chromosome damage to human lymphocytes, are difficult to extrapolate to effects on whole organisms due to the difference in the route of exposure and the uncertainty as to the magnitude of that exposure. There is also uncertainty as to what that effect might have on survival, reproduction and/or population effects, which are EFED toxic endpoints. While N-nitrosoatrazine has been shown to be mutagenic in genotoxicity tests (i.e., human lymphocytes), cancer bioassays in female mice and rats have failed to show carcinogenic responses following treatment with N-nitrosoatrazine.

p. 11. **NRDC & WWF Comment**: "Chlorinated atrazine metabolites act as endocrine-disrupting agents in aquatic amphibians, small mammals, and humans, causing abnormal reproductive organ development and cancers of the reproductive organs. The EFED risk assessment discusses briefly the toxicity of the degradates, compared to parent atrazine (EFEC [sic], p. 41-42). The Assessment [sic] notes that toxicity data for the degradates is not available for birds, fish, aquatic invertebrates, terrestrial plants, and acute oral mammals. This is a very serious data gap, given that the degradates are long-lived, and available data indicates that they are more chronically and acutely toxic than the parent atrazine (EFEC [sic], p. 42)."

**EFED Response**: The commenter has not specified chlorinated atrazine metabolite(s) of concern or provided any citation showing their endocrine-disrupting effects in aquatic amphibians or small mammals. EFED has not seen any wildlife toxicity studies for the above effects due to chlorinated atrazine metabolites. Acute and chronic mammalian toxicity data were available for some atrazine degradates. The base set acute ecotox tests have been identified as data gaps for the three major atrazine degradates (i.e., hydroxyatrazine, deethylatrazine, and deisopropylatrazine). Additional acute and chronic tests are held in reserve depending on the toxicity levels found in these acute tests.

Endpoints in ecological risk assessments have been limited to mortality and reproduction effects that pose a "significant adverse effect" to local, regional and national wildlife populations. If a

chemical causes endocrine effects, the effects should be expressed in reproduction studies.

p. 12. **NRDC & WWF Comment**: "Although the risk assessment identifies numerous scenarios under which atrazine may jeopardize endangered species, the document does not discuss whether or how EPA has consulted with the Fish and Wildlife Service (FWS) regarding compliance with the Endangered Specis Act (ESA)."

**EFED Response**: When the endangered species consultation procedures have been completed, the Agency will address the risks to endangered and threatened species.

p. 13. **NRDC & WWF Comment**: "Although water monitoring programs routinely detect atrazine levels above 20 ppb, these data likely underestimate actual levels substantially. Water monitoring sample sites are not necessarily correlated with atrazine use sites, and in particular, may miss sites where multiple fields are treated with atrazine resulting in pooled runoff into a common water source. Levels of atrazine under these conditions are likely to be many times higher than single field sites. Similarly, data collection is not timed to correspond with worst-case scenarios, such as closely following atrazine applications, or following large storm runoff events, and thus most often misses these highly toxic environmental exposures (EFEC [sic], 34, 44). Indeed, very high concentrations are not uncommon, reaching levels exceeding 500 ppm after storm runoff (EFEC [sic], p. 25), and often greater than 100 ppm after atrazine application (EFEC [sic], p. 24-25, 29)."

**EFED Response**: EFED recognizes these shortcomings of using monitoring data for assessing risks for pesticide use and has so stated these limitations. Since the PRZM-EXAMS model is limited to estimating pesticide concentrations in farm pond scenarios and there are no EPA models to estimate pesticide levels in flowing waters, the monitoring data provide some needed exposure information for these aquatic habitats. The Agency can use the monitoring data to assess risks in the flowing water habitats, or the risks to these areas may not be assessed at all. The level of risks from indirect effects in flowing waters is uncertain, because atrazine effects are reversible up to some uncertain period of exposure which marks the point at which plant reserves are expired and the plant dies. Pulse tests for different lengths of time and combinations with atrazine could provide the test data needed to know how long an exposure must be to kill different types of aquatic plants.

- p. 14. **NRDC & WWF Comment**: "In follow-up to the ecological risk assessment of atrazine, NRDC makes the five following requests to EPA:
- 1) That EPA clarify that atrazine's mode of action includes not only effects on the hypothalamic-pituitary-gonadal axis, but also a stimulatory effect on aromatase in numerous species. This mode of action must be included in both the ecological and the human health risk assessments."

**EFED Response**: EFED has already addressed this issue and relies on the results from reproduction studies to integrate all lethal and sublethal effects into the wildlife reproductive process.

- p. 15. **NRDC & WWF Comment**: "2) That EPA review and include, in the ecological risk assessment, the data submitted by Dr. Tyrone Hayes of U.C. Berkeley on the low-level of atrazine on amphibians."
- **EFED Response**: EFED will include the test results for the *Xenopus laevis* and the field observations on *Rana pipins* in the eco-risk assessment.
- p. 15. **NRDC & WWF Comment**: "3) That EPA immediately inform NRDC about the Agency's consultation with the Fish and Wildlife Service and efforts to address the effects of atrazine on endangered species."
- **EFED Response**: An endangered species consultation would not occur before the Agency has completed the reregistration process which includes addressing risks and a review of management options.
- p. 15. **NRDC & WWF Comment**: "4) That EPA include risk calculations for N-nitrosoatrazine and chlorinated atrazine metabolites in its ecological risk assessment; or alternatively, if quantification is not possible, that EPA gather the relevant data on this issue promptly and include an additional uncertainty factor in the risk calculations to account for the toxicity of the metabolites."
- **EFED Response**: As indicated above, toxicity studies with whole animals do not demonstrate the effects found in the *in vitro* tissue study by Meisner *et al.* (1993).

Commenter. Missouri Corn Growers Association (MCGA).

- p. 1. **MCGA Comment**: "Why the EPA has conducted a crude ecological risk assessment, even when its own scientific advisory panel advised a more sophisticated approach to understanding ecological risk is a mystery."
- **EFED Response**: This issue has been addressed previously. EFED determined that the greatest risks were indirect effects on the aquatic community from the loss of aquatic vegetative habitat. The PRA model as currently proposed does not have the capacity to predict or quantify indirect effects. Therefore, the PRA model was not used.
- p. 2. **MCGA Comment**: "We understand that the agency is suggesting aquatic life and farm ponds are impaired by atrazine use. However, the "model" farm pond described is far from typical. We understand the model farm pond is subject to the maximum application rate of atrazine, unrealistically high runoff from the heaviest rainfall, excessive transfer from soil erosion and consistent spray drift. That type of 'none real world' model is simply inaccurate."
- **EFED Response**: The pond scenario used by EFED is not the worst case scenario. The model is based on a one-hectare Georgia farm pond with a 10-hectare drainage basin. Missouri farm ponds typically have a larger relative drainage area than 10 to 1, hence the water concentrations

could be higher than for the Georgia farm pond. Also, EFED assessed risk for the typical use rate as well as for the maximum rate. Finally, the 90<sup>th</sup> percentile rainfall level is used, not the heaviest rainfall.

- p. 2. **MCGA Comment**: "Studies by our own MCGA Watershed Research, Assessment and Stewardship Project (WRASP) is beginning to yield data which shows that the use of no till farming, buffers and filters [sic] strips are dramatically reducing runoff from farm fields. ... Our intent is to use sound science to develop a list of management practices that farmers can utilize to help reduce any potential runoff even further that [sic] the above described methods. In other words, we are trying to 'maximize' our best management practices (BMP's) for producers."
- **EFED Response**: The Agency will consider management options to reduce risks, especially to aquatic areas. The results from your studies could provide useful information for assessing the efficiency of buffer and filter strips which may placed on the label to promote "best management practices."
- p. 2. **MCGA Comment**: "Bottom line, after more than forty years of use as an effective weed control tool for farmers, atrazine has demonstrated no real world risk to ecosystems."

**EFED Response**: Atrazine and no-till land use replaced the former, plowed field cultivation methods which had been responsible for the loss of top soils and sedimentation of streams and rivers. The no-till method for corn has improved water quality in many areas by reducing sedimentation. The commenter has provided no evidence to support their claim that atrazine has not had any "real world risk to ecosystems." Freemark and Boutin (1994) have concluded that the "Use of agricultural herbicides can alter biochemical and development processes in plants, plant morphology, and species abundance, composition and diversity, and the composition, heterogeneity and spatial interspersion of farmland habitats...these effects, to varying degrees, can impair organisms at other trophic levels (e.g., invertebrates, insects, mammals and birds). For example, plants are important to wildlife as shelter, nesting cover, and food resources."

Commenter: Triazine Network

## p. 1. Triazine Network Comment:

p. 2. **Triazine Network Comment**: "The EFED risk assessment is not consistent with USEPA guidance for performing an ecological risk assessment ERA), nor does it adequately reflect ECOFRAM (1999) recommendations and those of a peer-review panel of experts for performing an ERA as part of the FIFRA program."

**EFED Response**: EFED has revised the outline of the Atrazine RED to follow the 1998 ERA guidance. The indirect effects on the aquatic community reported from the loss of vegetative habitat were considered to be the area of greatest ecological concern. While some probabilistic methods were used in the ecological risk assessment, the fully probabilistic methodology (PRA) recommended by ECOFRAM (1999) was not used to assess risks, because the current PRA

methodology can not model indirect effects.

- p. 2. **Triazine Network Comment**: "The objectives of the EFED risk assessment are poorly defined and the assessment methods are either inadequate or inappropriate to achieve the poorly stated objectives. The assessment illustrates the problems identified in a June, 2001 USEPA Science Advisory Board report on the need to match management objectives with appropriate ecological risk assessment methods."
- **EFED Response**: The Atrazine RED has been revised to include the problem formulation connecting the preliminary assessment to the refined risk assessment.
- p. 2. **Triazine Network Comment**: "The EFED risk assessment does not represent a weight-of-evidence approach. The assessment provides inadequate, and at times incorrect or inappropriate, consideration of the available scientific literature."
- **EFED Response**: The adverse effects cited in the Atrazine RED are generally substantiated by more than one reference providing a weight-of-evidence approach to various atrazine-related effects. The toxic effects reported in a series of Kansas pond studies at  $20~\mu g/L$  atrazine demonstrated wide-ranging and reoccurring, serious adverse effects on the aquatic community. The only effect not found in more than one study was the reduced recruitment of young bluegill, because the experiment has never been repeated with bluegill sunfish.
- p. 2. **Triazine Network Comment**: "The EFED risk assessment does not represent a 'higher tiered' or 'refined risk assessment'. The assessment relies on models using the highest exposure point data and the lowest toxicity benchmarks, an approach inconsistent with ECOFRAM and USEPA guidance, which specifies that a higher tiered ERA minimize reliance on overly conservative assumptions and simplistic models."
- **EFED Response**: EPA guidance provided for the Tiered PRA assessment begins with the simple GENEEC Model as Tier I. If there are possible risks to aquatic organisms, proceed to Tier II and the use of the PRZM-EXAMS Model. Higher tiers in the ecological risk assessment have not yet been specified, and are only in a proposal stage.

Since there is substantial monitoring data on atrazine levels in surface waters, exposures in the next tier were based on monitoring data in larger streams, rivers and reservoirs. The use of monitoring data for assessing aquatic risks is unusual because there are rarely enough monitoring data on a chemical to be useful. Monitoring data, such as that available for atrazine, are not focused on proximity to use sites and timed to atrazine applications; hence the monitoring data may underestimate environmental exposures. Acute risks were generally low for mammals, birds, fish and aquatic invertebrates. Chronic exposure levels were difficult to determine from the monitoring data. A number of endpoints were identified at various increasing atrazine concentrations. From this distribution, the area of greatest concern appeared to be the indirect effects to the aquatic community in a series of Kansas pond studies. Consequently, EFED focused on the area of atrazine effects which appeared to pose the greatest risk (i.e., indirect

effects on the aquatic community). Unfortunately, the PRA methodology could not be used for a "higher tiered" assessment, because the PRA model can not predict or quantify risks due to indirect effects.

PRA also can not estimate risks when insufficient toxicity and/or exposure data are available. For example, the toxicity data are insufficient to assess time-related effects on toxicity of atrazine on aquatic plants. Time-related toxicity data for atrazine are available only as three tests for *Lemna gibba*, which show lower toxicity values on Day 14 than after Days 5 and 7.

p. 2. **Triazine Network Comment**: "Inaccurate conclusions that atrazine poses a serious risk to aquatic life and mammals in chronic exposure scenarios is largely based on generic and nonspecific information, which are not adequately supported by a detailed evaluation of the scientific literature regarding Atrazine use, occurrence in the environment, and behavior in aquatic ecosystems."

**EFED Response**: The risks to aquatic organisms in lentic habitats reflect monitoring data exposures and toxic effects associated with each type of aquatic habitat. For example, lake and reservoir effects are based on monitoring data for lakes and reservoirs and atrazine effects in lentic waters, while the risks for streams match stream monitoring data to stream toxic effects. Since there was little or no monitoring data for farm-sized ponds, the atrazine concentrations were estimated using the PRZM-EXAMS Model. Risks in lentic habitats were greater than in lotic areas, because atrazine effects on plants are time dependent and exposures in flowing waters are usually short term and plants may recover.

The indirect effects on terrestrial mammals and birds from changes in the vegetative habitat were derived from Freemark and Boutin (1994). These indirect effects resulting from alteration in vegetation in and around treated fields were generalized from herbicide use in agriculture. The Triazine Network is welcome to submit any additional information that it deems relevant.

p. 3. **Triazine Network Comment**: "Farmers use significantly less product today than they did in the early years of availability. And they used even less in the past decade, following label changes in 1990 and 1992."

**EFED Response**: The present requirement was to review current maximum label use rates and typical use rates to assess ongoing risks to terrestrial and aquatic organisms.

p. 3. **Triazine Network Comment**: "Farmers have dramatically increased the adoption of conservation practices in the past few decades. And within that general heading, have greatly increased practices focused on water quality improvement in the past ten years."

**EFED Response**: Water quality improved when no-till corn was introduced, reducing soil erosion and sedimentation in streams and rivers. The use of herbicides which permit no-till corn has had other effects on fish and wildlife. The EPA assessment included evaluation of recent monitoring data. The Triazine Network may submit data which show the relationship between

specific agricultural practices and concentrations of atrazine in runoff.

- p. 3. **Triazine Network Comment**: "The ecology of farm ponds and streams has not changed in the forty years that farmers have been using atrazine. Apparently at risk wildlife do not read and respond to EFED assessments, but manage to thrive and rebound when exposed to the actual levels of atrazine found in the real world."
- **EFED Response**: The Triazine Network has provided no evidence to support their claim that the ecology of farm ponds and streams has not changed in the forty years that farmers have been using atrazine. They are welcomed to submit biological census data or ecology studies on farm ponds that address conditions over the last forty years.
- p. 9. **Triazine Network ENVIRON Comment**: "The EFED risk assessment suffers from a severe lack of organization."
- **EFED Response**: Much of the content concerning endpoints, executive summary, "preliminary" and "refined assessments" was present in the EFED document, but not well organized. EFED agrees and has reorganized the atrazine document and added a "Problem Formulation section."
- p. 10. **Triazine Network ENVIRON Comment**: "The document sorely needs a properly organized Analysis section at the beginning of the document. According to USEPA (1992)<sup>3</sup>, an Analysis section should include, at a minimum: ...."
- **EFED Response**: The Agency has transferred these sections to the Appendices to shorten and simplify the large risk assessment documents. The focus of the main body of the RED document is to concisely address the areas of risk for the multiple uses of a pesticide. All supporting data and models are documented in the Appendices.
- p. 10. **Triazine Network ENVIRON Comment**: "The objectives of the EFED risk assessment are poorly defined and the assessment methods either inadequate or inappropriate to achieve the poorly stated objectives."
- **EFED Response**: The RED was modified and statements for problem formation from one tier to the next tier were added.
- p. 11. **Triazine Network ENVIRON Comment**: "What animals and birds were considered in the chronic terrestrial exposure model? EFED refers to animals of generic body weights(5 [sic] g, 35 g, and 1000 g); what species are these generic assumptions relevant to within the different agricultural regions where atrazine is used? What are the specific parameters for food uptake? How was atrazine's application period and the feeding / residence time for target [sic] species considered in the exposure models? Were animals to feed exclusively on food items from fields treated with atrazine? How realistic were the terrestrial exposure scenarios? (pg 7)"

**EFED Response**: The test species yielding toxicity values are surrogate species for any relevant avian or mammalian species that may be found in treated areas. While a particular species may have a limited local or regional distribution, there are other species in the other areas which occupy an equivalent ecological niche. An assessment of chronic effects is based on initial residue levels because the duration of exposure producing chronic toxicity is uncertain.

The justification and methodology for the use of generic body weights for mammals is provided in the "Draft Mammal Risk Assessment Guidance Paper" dated March 2, 1995). The generic body weights and respective food consumption rates permit the estimation of risks for animals of different body sizes and varying dietary content. This methodology uses the available acute mammalian  $LD_{50}$  toxicity values to estimate dietary toxicity values, rather than require additional toxicity tests on mammals similar to the subacute  $LC_{50}$  values for two bird species. The 15, 35, and 1000 g mammalian body weights include young and/or adult life stages of small mammals such as voles, shrews, rats, kangaroo rats, rabbits, hares, mice, ground squirrels, squirrels, chipmunks and ground hogs, which have diets that include grasses, foliage, fruits, seeds, insects, and earthworms.

According to Gusey and Maturgo (1973), the many bird species (young and/or adults) feeding or brood-rearing in corn fields include: the northern bobwhite, scaled quail, ringnecked pheasant, ruffed grouse, sharp-tailed grouse, Hungarian partridge, prairie chicken, whistling swan, snow goose, mourning dove, white-winged dove, crow, redwing blackbird, yellow-headed blackbird, dabbling ducks, wood duck, sandhill crane, geese, wild turkey, cardinals, grackles, grosbeaks, jays, meadowlark, white-breasted nuthatch, raven, robin, sparrows, thrasher, titmouse, towhee and woodpecker. Many of these same bird species also feed in sorghum fields. Some of these avian species feed in corn and sorghum fields year round.

The exposure levels for mammalian and avian risk assessment were a range of values based on atrazine levels on short grass (240 pp/lb ai./A), long grass (110 ppm/lb ai/A), foliage and small insects (158 ppm/lb ai./A) and fruit and large insects (15 ppm/lb ai./A). Risk factors included in the wildlife dietary exposures are oral preening and grooming, dermal absorption, and inhalation. Only at the upper end of the risk quotient range were animals assumed to feed exclusively on food items from the atrazine-treated fields.

p. 11. **Triazine Network - ENVIRON Comment**: "It is widely understood that any activity that alters native or resident vegetation (and thus habitat) may result in altered wildlife feeding and foraging behaviors. The issue undefined in the EFED risk assessment is whether the changes induced by atrazine residues in spray drift or surface runoff result in significant changes (i.e., permanent or short-lived) and if so, for how long. (pg 7-8)"

**EFED Response**: The indirect impacts of atrazine use on terrestrial wildlife came from an article on agricultural herbicide impacts (Freemark and Boutin, 1994). The article identified herbicide effects on non-target plants, soil organisms, insects and other invertebrates, mammals and birds. Atrazine effects on plants were not directly specified, but Fox (1964) reported that atrazine decreased the abundance of earthworms, wireworms and springtails. Fox concluded that

when vegetative cover was decreased significantly, soil invertebrates were less abundant; when only the floristic composition was modified, soil fauna were not greatly altered. The reduction in abundances of these soil organisms by atrazine means less food resources for wildlife. The EFED risk assessment indicated that indirect effects to terrestrial animals is a general effect of herbicides, not just atrazine. For this reason and the low acute risks to birds and mammals, EFED did not proceed with a higher level risk assessment for terrestrial animals.

p. 11. **Triazine Network - ENVIRON Comment**: "It appears that the generic discussion of ecological principles presented in the document (pg 20 -21) is supported by only one study, Kettle et al. (1987). Specifically, how is the information in Kettle et al. (1987) relevant to current atrazine application rates and usage in different agricultural environments? What reference points are evaluated to compare ecological conditions in the presence and absence of atrazine inputs to farm ponds and other aquatic environments? Why does EFED conclude that a single study is sufficient to understand the fate of atrazine in farm ponds and other aquatic environments, particularly in light of information presented in Giddings et al. (2000) concerning the limitations of the Kettle et al. study?

**EFED Response**: Kettle *et al.* (1987) and DeNoyelles *et al.* (1982) reported the results from Kansas ponds treated on 24 July 1979 and monitored until the following spring. Dewey (1986) repeated the study from 30 May to September 28, 1981 and also observed reductions in periphyton, macrophytes, macrophyte habitat and herbivorous insects. In the revised chapter, EFED has also examined data from microcosm and mesocosm studies cited by the registrants as well as additional publicly available literature. Results from these studies confirmed the original conclusions as well as added information on effects at even lower concentrations than those discussed in the original EPA assessment.

p. 11. **Triazine Network - ENVIRON Comment**: "Presumably, the information tabularized on pages 21-22 indicates atrazine concentrations in finished community water supply (CWS) wells.

**EFED Response**: The purpose of presenting the results of the selected CWSs on pages 21 and 21 is to demonstrate that even for finished (i.e., treated) drinking water, the atrazine concentration can be higher than 20  $\mu$ g/L (ppb). EFED used these actual monitoring results to support the conclusion that the atrazine concentrations of raw waters for these systems, which could have possible ecological impacts, could be even higher.

p. 11. **Triazine Network - ENVIRON Comment**: "EFED provides an inadequate explanation of why it is appropriate to merge CWS and USGS reservoir data from different ecological and agricultural regions. Why is it appropriate to merge these seemingly different data sets? Where have the data been fully evaluated by EFED?"

**EFED Response**: EFED did not merge CWS and USGS reservoir data from different ecological and agricultural regions. Rather EFED discussed each data set on its own. Similar to the comment above, the use of CWS and USGS reservoir results on atrazine concentrations in treated water is to emphasize that the concentrations of the untreated raw water can be even

higher, which may have potential ecological concerns.

p. 12. **Triazine Network - ENVIRON Comment**: "Given EFED's reservations that NAWQA data may not be appropriate to evaluate atrazine surface runoff, why did EFED choose to consider the data at all? What do environmental reference conditions look like (i.e., conditions in the absence of atrazine occurrence in the environment; pg 34)?

**EFED Response**: EFED expressed cautions about the interpretation of atrazine concentrations reported in the NAWQA data because the NAWQA sampling times and sampling sites were not necessarily related to the timing of atrazine applications and runoff events. The NAWQA monitoring program is not likely to measure peak and other high atrazine concentrations and is may underestimate atrazine concentrations in smaller streams and rivers adjacent to atrazine-treated fields. The purpose of NAWQA is to assess the overall water quality of national water bodies. In addition to the "indicator" sites representing "predominant" land use, such as agriculture and urban sites, which are usually on the order of 20 to 100 square miles, the study design also investigates the "integrator" sites to represent large rivers and mixed land uses, which are on the order of 500 to greater than 1000 square miles. EFED has used the results of agricultural indicator sites to represent the aquatic exposure of stream, river and reservoir environments. Again, these are the actual monitoring results. EFED's caution is about the sampling scheme, since sampling intervals varied from weekly to monthly. Due to the spread of sampling frequency, EFED can not rule out the possibility of missing the peak atrazine concentration.

EFED decided to use atrazine data in the NAWQA to assess risks to aquatic organisms in a stream or river because EFED does not currently have a runoff model to estimate pesticide concentrations which spray drift and/or runoff into flowing water environments. The NAWQA database has a considerable amount of data on atrazine from its wide-spread use; therefore, the use of NAWQA data on atrazine was considered appropriate to assess risks for streams and rivers. Even if NAWQA does not yield the highest pesticide concentrations, the NAWQA data provides real exposure data for atrazine over a wide range of stream and river sizes and localities.

The Agency does not use ecological reference sites for assessing risks to pesticides. A reference site is typically used as a control when conducting an experiment.

p. 12. **Triazine Network - ENVIRON Comment**: "Where is the Louisiana data fully presented and evaluated by EFED? What do reference conditions look like (i.e., conditions in the absence of atrazine; pg 36-37)? Where is the analysis of an ecological reference site to compare ecological conditions in the presence and absence of atrazine inputs? Isn't possible that atrazine may have little, if anything, to do with observed conditions?"

**EFED Response**: Similar to the previous answer, the Louisiana monitoring data are used to establish the possible exposure level for aquatic exposure purposes.

- p. 12. **Triazine Network ENVIRON Comment**: "Given EFED's reservations that data from Louisiana and the Chesapeake Bay may not point to atrazine as the source of depressed ecological conditions, why does EFED proceed with an analysis that portrays atrazine as a primary source of environmental conditions in these two distinctly different aquatic environments?"
- **EFED Response**: As in the case of EFED's use of NAWQA data from streams and rivers, EFED is concerned that the monitoring data in these two large estuaries are unlikely to measure peak and other high atrazine concentrations in areas adjacent to treated fields on the end of estuarine habitats. Despite these shortcomings, EFED used the atrazine concentrations to assess the possibility of risks in estuarine habitats where sugarcane and corn are grown adjacent to estuaries, because EFED does not have a model to estimate atrazine levels from spray drift and runoff. EFED assessed the risks based on the levels of atrazine measured in the monitoring programs. EFED did not identify atrazine as the **primary source** of environmental conditions in these two estuarine habitats. No attempt was made to compare the effects of other sources such as POTWs and sedimentation against the potential risks from atrazine.
- p. 12. **Triazine Network ENVIRON Comment**: "EFED appears to support speculation that conditions in Chesapeake Bay are due to atrazine. Field studies specifically focused on areas where atrazine occurs in the Chesapeake coupled with reference sites where atrazine does not occur should be included in the discussion, (pg 40). Where is the analysis of an ecological reference site to compare ecological conditions in the presence and absence of atrazine inputs? In the absence of any detailed evaluation, it is entirely inappropriate for EFED to conclude that conditions in Chesapeake Bay are likely due to atrazine."
- **EFED Response**: Many of the effects seen in the Chesapeake Bay could be due atrazine (such as loss of aquatic vegetation, suspended sediments, sedimentation, etc.). But there are other sources of pollutants that enter the Chesapeake Bay, including sediments from the rivers; nutrients from POTWs, crabbers and oysterman that dredge and drag trawl over the vegetated areas, suspending sediments and uprooting vegetation; oils and other chemicals washed off the highways into streams and creeks and carried into the Bay, etc. EFED's assessment was limited to assessing the potential for risks to the Bay from direct and indirect effects of atrazine.
- p. 13. **Triazine Network ENVIRON Comment**: "The approach adopted by EFED to compile and evaluate the large volume of scientific literature on atrazine appears inadequate and does not reflect the weight of evidence approach recommended by ECOFRAM (1999) and in USEPA ERA guidance documents<sup>3,4,6,7</sup>. For example, EFED is strongly encouraged to adopt an approach similar to that used by Solomon et al. (1996, 2001)<sup>11,12</sup> to evaluate atrazine in North American surface waters and chlorpyrifos in terrestrial environments. Both approaches are consistent with USEPA ERA guidance and adhere to the ECOFRAM approach."
- **EFED Response**: EFED conducted both a preliminary terrestrial and a refined aquatic risk assessment. The aquatic EECs were estimated based on modeling atrazine exposures using the PRZM-EXAMS Model for a farm pond scenario. EFED assessed the risks to terrestrial wildlife

and, at least acutely, the risks were found to be low. Chronic risks, if any, were moderate. Risks to non-target crops were low to moderate for spray drift, and moderate to high for non-target crops in dry and semi-aquatic areas, due to atrazine levels in soil from the combination of spray drift and runoff. The acute risks to aquatic organisms in the farm pond were low for fish, low to moderate for aquatic invertebrates and moderate to plants. The aquatic chronic risks for atrazine were moderate for fish and aquatic invertebrates. The standard assessment suggested that the areas of highest potential risks appeared to be non-target crops and aquatic plants. Since there is no higher tier risk assessment for terrestrial plants, the area which EFED focused on was the aquatic plants and indirect impacts on the aquatic community.

The refined atrazine risk assessment by EFED was conducted using atrazine exposure levels from the NAWQA database. The use of atrazine on major crops such as corn, sorghum and sugarcane involves the treatment of crops adjacent to a variety of aquatic habitats. Corn fields are adjacent to a greater number of habitats than any other crop in the US, from the shores of the Chesapeake Bay in Maryland and Virginia along streams, rivers, marshes, swamps, farm ponds, and lakes, on mountain sides in Appalachia and nearly in a continuous belt across the midwest. Sorghum is generally grown in drier regions than where corn is grown, but there too are streams, rivers, farm ponds, lakes and marshes. Sugarcane is grown in low rich soils of southern Louisiana and southern Florida, edged by canals, rivers, streams, marshes, swamps and estuaries.

EFED addressed some of the potential risks of atrazine used on fields adjacent to four types of aquatic habitats. A preliminary risk assessment for the farm pond used model estimates of atrazine concentrations. Since the NAWQA database provided no measured concentrations of atrazine in farm ponds, EFED was limited to the PRZM-EXAMS Modeling EEC data for the ponds. Atrazine exposure concentrations found in the NAWQA database were generally measured in aquatic areas such as lakes and reservoirs, streams and rivers, and two important estuarine areas where atrazine is applied to crops (i.e., the Chesapeake Bay and the Terrebonne Basin in southern Louisiana). While EFED recognizes that the NAWOA sites and sampling times are not correlated to atrazine applications, periods of runoff, or close proximity to treated fields, the NAWQA database provides atrazine exposure levels in aquatic areas for which EFED lacks the models to estimate pesticide levels. To assess the potential risks for each of these four aquatic habitats, the EECs or NAWQA levels of atrazine were compared to the results of atrazine field studies and toxicity data appropriate for each aquatic habitat. EFED compiled and evaluated a large volume of scientific literature on atrazine. Some aquatic habitats had more information on the toxicity of atrazine than others (i.e., most field effects data were on ponds and estuarine habitats). The effects of concern identified in this tier of the assessment where indirect effects on the aquatic community resulting from the loss of vegetative habitat and nutritional species of plants and algae. The risk assessment has been reorganized along the lines of the ECOFRAM and USEPA ERA guidance documents. Unfortunately, the current PRA methodology used by Solomon et al. (1996, 2001) can not be used to assess adverse indirect effects.

p. 13. **Triazine Network - ENVIRON Comment**: "Furthermore, EFED is strongly encouraged to reconsider the risk assessment methods and weight of evidence used by Giddings et al.

(2000)<sup>14</sup>. The technical disagreements between EFED and the Registrant's ecological risk assessment experts regarding various specific aspects of EFED's December 8, 2000 draft environmental fate and effects chapter remain largely unresolved<sup>14</sup>. Comparing the two documents directly, Giddings et al (2000) appears to convey a careful and thorough review of the scientific literature and adherence to USEPA ERA guidance. Regrettably, the EFED risk assessment does not appear to represent the same level of thoroughness and scientific rigor."

**EFED Response**: The risk assessment by Giddings *et al.* (2000) was reviewed and several concerns were identified, including the lack of problem formulation, the absence of sensitivity tests, and the use of unverified models to estimate atrazine EECs. A major difference between the two reports is the interpretation of the results of a series of atrazine tests in Kansas ponds by the University of Kansas. At 20  $\mu$ g/L, atrazine affects a number of populations, including the reduction in some phytoplankton and zooplankton species (DeNoyelles *et al.*, 1982); reductions in macrophytes, except *Chara*, reductions in some populations, diversity and reduced emergence of some aquatic insects (Dewey, 1986); and 60 to 90 percent reductions in macrophytes, 96 percent reduction in number of surviving young bluegill sunfish, fewer insects per fish stomach and reduced number of insect taxa (i.e., diversity) in fish stomachs (Kettle *et al.*, 1987).

The direct effects of atrazine on macrophytes as a habitat for aquatic organisms and its indirect effect on the survival of young fish and aquatic insect populations are major areas of concern to EFED. The presence of atrazine in an aquatic habitat, such as ponds, lakes, marshes, swamps and possibly estuarine areas, poses a risk to some aquatic plants and algae. The longer the exposure, the more likely the plant or algae will consume its energy reserves and die, resulting in the loss of vegetative habitat. There are then indirect adverse effects on other parts of the aquatic community. It is uncertain whether the duration of atrazine exposures from applications to different fields within a drainage area might also have prolonged effects and cause the death of vascular plants and vegetative habitats in small streams or even slow-flowing rivers. Data evaluated by Giddings, *et al*, support these concerns, as well.